

Statement submitted July 10, 2005.

My name is Walter Wolf, PhD, Distinguished Professor of Pharmaceutical Sciences, and Director, Pharmacokinetic Imaging Program, University of Southern California. I was also the Chair, since its inception (April 8, 1976), of RDRC #36, and I was Director of the Radiopharmacy Program at USC from 1968 through 1995, when the scope of the Radiopharmacy Program was expanded to Pharmacokinetic Imaging. As a consequence of the uncertainties of the status and the lines of responsibility of the RDRC, and the liability of its members, we requested on January 26, 2005 that RDRC #36 be placed on inactive status. That became effective by letter of March 2, 2005.

On October 24, 2004 I had submitted a first set of comments concerning docket 2004-0432, which is attached hereby. In that submission I had stated:

1. The main concern I have, however, is with the fact that there is no clear understanding of what is the liability of the members of the RDRC's. I had raised that question in February of 2004, and on 2/20/04 I had written to the FDA, attn. Dr. Orhan Suleiman:

What is our liability coverage as an FDA committee?

When we talked [earlier today] we discussed whether we were an FDA committee operating locally, or whether we were an institutional committee approved by the FDA.

My reading of 21CFR361.1 is that we are an FDA committee, and function for and in behalf of the FDA.

The first part of 21CFR361.1(b) reads: ...

(b) The conditions under which use of radioactive drugs for research are considered safe and effective are:

(1) Approval by Radioactive Drug Research Committee. A Radioactive Drug Research Committee, composed and approved by the Food and Drug Administration in accordance with paragraph (c) of this section,

There is no provision that I can read in either section (b) or (c) that suggests that the RDRC is anything but an FDA committee, rather than an institutional committee approved by the FDA. Indeed, in section (c)(1) it states:

.... A Radioactive Drug Research Committee shall be either associated with a medical institution operated for care of patients and with sufficient scientific expertise to allow for selection of committee members from its faculty

My reading of this section is that the association is intended to allow for the availability of faculty with the appropriate expertise. And in all my years as Chairman of RDRC#36, whenever we proposed a new member, we submitted his/her CV to the FDA, and at no time were we asked to indicate any institutional approval or involvement in such appointments.

On 2/20/04 Dr. Orhan Suleiman advised me that "We are formally raising the question with our FDA lawyers, which unfortunately will take some time". Last time I inquired, a few weeks ago, I was advised that there was still no response from the FDA lawyers.

The reason this question becomes even more important at this time is that the identification of toxic effects of compounds that have not been tested extensively before in animals and humans is not trivial, and there may be a potentially significant liability when administering a compound whose toxicity is not fully known to a human being. Who has the liability for any adverse effects, and what is the protection afforded to members of the RDRC for potential claims of damages (whether justified or not)?

Inasmuch as the RDRC's are FDA committees, what is the liability protection provided by the FDA to the members of the RDRC?

2. As of today (10 July 2005) I have not seen clear answers to these questions. Indeed, a perusal of the presentations made by several members of the FDA (R Fejka, OH Suleyman and MR Walsh) at the 2005 annual meeting of the Society of Nuclear Medicine [e.g. Drug Safety And Quality For Research Conducted Under An Radioactive Drug Research Committee (RDRC)] restates that the RDRC is a:
 - a. Committee consisting of qualified members, approved by the FDA [slide 2]
 - b. Each Radioactive Drug Research Committee shall be specifically approved by the Center for Drug Evaluation and Research of the Food and Drug Administration. [slide 4]
3. At no point in any of the documents that have been presented so far is there any indication or suggestion that an institution (University, Hospital) is involved in any formal manner.
4. In addition, and by letter from George Mills (Director, Division of Medical Imaging and Radiopharmaceutical Drug Products, Office of Drug Evaluation III, Center for Drug Evaluation and Research, FDA), dated 10-28-04, I was advised:

We have consulted the FDA's Office of the Chief Counsel and the Department of Health and Human Services' Office of General Counsel regarding your inquiry and they have provided the following:

Regarding possible coverage under the Federal Tort Claims Act ("FTCA"), 28 U.S.C. §§ 1346(b), 2401(b), and 2671-80 for a RDRC established pursuant to 21 C.F.R § 361, we believe that there has been no Congressional waiver of sovereign immunity in the case of RDRCs, as required for extension of FTCA coverage.

Actions under the FTCA must be based on an allegedly tortious act of an "employee of the government," a term that is further defined by statute. See 28 U.S.C. § 2671. As you are aware, RDRCs are independent peer review groups comprised of various consultants in highly specialized medical disciplines. As such, these groups are not a part of the FDA or any other federal agency, nor are they or their members "employees" of the agency. Because RDRCs do not have the indicia of federal agency or employee status, the FTCA does not apply to their activities. Accordingly, liability rests with their associated institution.

5. Thus, and inasmuch as the FDA's Office of the Chief Counsel and the Department of Health and Human Services' Office of General Counsel have determined that: "**RDRCs do not have the indicia of federal agency**", it is obvious that members of the RDRC are acting as individuals with NO liability protection except from their own personal insurances, inasmuch as they have not been appointed by any institution other than the FDA, nor is there any statutory evidence that they are acting in behalf and at the behest of any institution, other than the FDA.
6. Based on the above information, and until such time as proper lines of responsibility, authority and liability protection are defined, it would be unconscionable to place individuals in a significant risk situation. It continues to be my contention that this legal issue needs to be fully resolved BEFORE the FDA can expect members of the scientific and medical community active participation in RDRC activities.